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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,054

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Robert E. Richard

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EXAMINER

HUGHES, ALICIA R

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,054	<b>Applicant(s)</b> RICHARD ET AL.	
	<b>Examiner</b> ALICIA R. HUGHES	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-13,16-18 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11 sheets</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1, 3-13 and 15-30 are pending. Claims 1, 3-13, 16-18 and 30 are the subject of this Office Action. Claims 15 and 19-29 have been withdrawn from consideration, being drawn to a non-elected invention. Applicants cancelled claim 2 and added claim 20 in their filing of 30 January 2009.

Applicants' arguments filed on 30 January 2009 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

### ***Information Disclosure Statements***

Applicants note in their remarks of 09 January 2009 that two Information Disclosure Statements had been submitted in this case, noting January 2004 and March 2005 as the submission dates. The Examiner does enclose herein, those acknowledgments.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-13, 16-18 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent Application No. 10/894,400. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1, 3-13, 16-18 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-23 of U.S. Patent Application No.

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10/632,008. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

Claims 1, 3-13, 16-18 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 7241455, which was previously U.S. Patent Application No. 10/409,358. The rejection as written in this Office's Action of 14 June 2007 is extended and fully incorporated herein by reference.

In response the above rejections, Applicants, in their remarks of 14 December 2007, 17 October 2008 and now 30 January 2009 have declined to discuss the merits but rather, have opted to address these provisional rejections at a future time when these rejections only remain. Until such time, the rejections are considered proper and therefore, maintained.

### ***Claim Rejection – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-13, 16-18 and 30 are rejected under 35 U.S.C. 103(a) as being obvious over Phan et al in view Cruise in view of Pinchuk et al and in further view of Furst.

The teachings of each of the above, as noted in this Office's previous actions in this case are incorporated herein by reference in their entirety.

As noted above, the Applicants have canceled claim 2 and incorporated the limitations of the same into claim one, from which all other claims herein depend. Previously, claims 2 and 3

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were rejected under Phan et al in view of Cruise, but given the recent amendment, Cruise et al must now necessarily be utilized to reject all claims. Further, the addition of the limitations of previous claim 2 now also undermines the rejection of claims 1 and 4-9 as anticipated by Phan et al. The same are now deemed obvious, also.

Applicants now argue that the Office has not established a *prima facie* case of obviousness, because Phan et al emphasizes the cross-linking of polymers. Applicants go on further to point out examples in Phan et al where by cross-linking there is exposure to irradiation in the form of a 2.5 Mrad electron beam. Importantly, these 2.5 Mrads do read on the instant invention, which calls for a radiation dose that is at least 100,000 rads and claim 30, which has a range of 1 Mrad to 10 Mrads.

Further, Applicants' argue that there is no teaching or suggestion in Phan et al of polymers in which radiation is used to increase release of a therapeutic agent from a polymer is unfounded. Rather, as noted in the Office Action of 17 April 2008, it logically follows that the same therapeutic agent comprising the same polymeric release region is used in the same host, subject to a radiation dose that gives the same effect to the same patient population (Please see Col. 6, lines 29-33). And further as noted prior, by Applicants' own account,

“when polymers are exposed to radiation, at least two *reactions are believed* to occur” and “[c]rosslinking *generally* results in ...[and c]hain scission, on the other hand *generally results* in ...While polymers *may display* both types of reactions, one type of reaction will typically dominate. For increased release, *it is preferred to use polymers* in which chain scission reactions dominate.” (Emphasis added).

Applicants also argue that since Cruise et al teach hydrogels, that it is not germane to the instant invention. This one teaching does not negate the other teachings in Cruise et al as noted

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prior in the record and further, all other contentions with regard to Cruise et al and its teachings are but allegations that lack factual support. As a result, they are assigned no patentable weight.

Applicants also argue that there is no support to combine the teachings of Phan et al with the teachings of Pinchuk, because Pinchuk does not teach or suggest the use of any radiation treatment. By Applicants' own admission, however, Pinchuk does disclose the release of therapeutic agents over time. Given the state of the art, particularly the release of therapeutic agents over time in stent systems, and as well, the reasons made previously of record for combining the references, the Applicants' assertion that there is not support to modify the teachings of Phan et al with the teachings of Pinchuk is but an allegation lacking factual support.

With regard to the Furst reference, Applicants also argue that support for its use cannot be sustained, most notably because the amount of radiation used in Furst is less than 2000 rads. The Furst reference is not utilized as a single reference to anticipate the instant invention. Rather, it is used in concert with, to modify other references that teach stent technology. It would not be unreasonable or outside the motivation of one of ordinary skill in the art to modify Furst et al by the teachings in the other cited references to arrive at the radiation dosage taught by the instant invention.

In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to develop a stent with a polymeric release region and therapeutic agent wherein the polymeric release region would be treated with a radiation dose in excess of 10,000,000 rads to increase the cumulative release of the therapeutic agents therein.

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### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished



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applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/  
Examiner, Art Unit 1614

/Raymond J Henley III/  
Primary Examiner, Art Unit 1614